

PATENT APPLICATION

Our File No.: 20050515.ORI

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App Naomi Chayen et al

: October 13, 2005

S.N.

10/534,088

: Art Unit unknown

Filed : May 6, 2005

For

MESOPOROUS GLASS AS NUCLEANT FOR MACROMOLECULE CRYSTALLISATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## INFORMATION DISCLOSURE STATEMENT UNDER RULE 1.56

Applicant(s) herein make available to the Patent and Trademark Office a copy of Form PTO-1449 which lists the following document(s), copies of which are enclosed. This Information Disclosure Statement is being filed in accordance with the following provision(s):

- [ ] 37 CFR 1.97(b)(1) Within three months of the filing date of the national application. No fee is required.
- [ ] 37 CFR 1.97(b)(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in the international application. No fee is required.
- [X] 37 CFR 1.97(b)(3) Before the mailing date of a first Office Action on the merits. No fee is required.
- [ ] 37 CFR 1.97(c) After the periods specified in 37 CFR 1.97(b), but before the mailing date of either: (1) a final action under § 1.113 or (2) a notice of allowance under § 1.311, whichever occurs first.

- [ ] The undersigned hereby certifies that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement; or
- [] The undersigned hereby certifies that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of this statement; or
- [] Enclosed is a check in the amount of \$200.00 for the fee set forth in 37 CFR § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 08-1265. Two copies of this sheet are enclosed.
- [] 37 CFR 1.97(d) After the mailing date of either (1) a final action under § 1.113 or (2) a notice of allowance under § 1.311, whichever occurs first, but before payment of the issue fee.
- [ ] Applicant(s) hereby petition the Commissioner of Patents and Trademarks to consider this information disclosure statement. Enclosed is a check in the amount of \$130.00 for the petition fee set forth in § 1.17(i)(1). The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 08-1265. Two copies of this sheet are enclosed.

The listed documents are brought to the Examiner's attention because they are known to the applicant and/or the applicant's attorney and may be considered by the Examiner to be material to his/her examination. This listing should not be construed as

representation that a search has been made or that no better art exists. No inference should be made that the documents are in fact material merely because they are referenced herein. Moreover, no representation is made that any brief descriptions of the references herein necessarily describe the most material aspects of the references. Further, by this listing, the applicant is not making any admission regarding the relative dates of the invention and listed disclosures.

The Examiner is requested to consider carefully the complete text of these documents in connection with the examination of the above-identified application in accordance with 37 CFR 1.104(a). It is requested that the documents listed on the attached Form PTO-1449 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. 1302.12), and that the Examiner initial and return a copy of the form to evidence consideration of the documents.

Dated: October 13, 2005.

Respectfully submitted,

NIKOLAI & MERSEREAU, P.A.

C. G. Mersereau

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## CERTIFICATE OF MAILING

I hereby certify that the foregoing Information Disclosure Statement Under Rule 1.56, a Form PTO-1449 and a copy of the references cited to be filed in connection with application Serial No. 10/534,088 of inventor(s), Naomi Chayen et al, filed May 6, 2005, for "MESOPOROUS GLASS AS NUCLEANT FOR MACROMOLECULE CRYSTALLISATION", are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 14, 2005.

Barbara L. Davis

Secretary to C. G. Mersereau

Date of Signature: October 14, 2005

(2-92) Sheet 1 of 4

Form PTO-1449				Document Number 20050515.ORI			Application Number 10/534,088		
INFORMATION DISCLOSURE CITATION IN AN APPLICATION				Applicant Naomi Chayen et al					
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EXAMINER INITIAL	DOCUMENT NUMBER		DATE	NAME		CLAS	S SUBCLASS	FILING DATE IF APPROPRIATE	
	4,171,544		10/23/79	Hench et al.					
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	WC	02/088435	11/07/02	WIPO					
	1	OTHER DO	CUMENTS (In	cluding	g Author, Title	, Date,	Pertinent	Papers, Etc.)	
		Blow et al, PROTEIN SCIENCE, Control of Nucleation of Protein Crystals, Vol. 3, 1994, pp. 1638-1643					Crystals, Vol.		
		Chayen et al, J. APPL. CRYST. An Automated System for Micro-Batch Protein Crystallization and Screening, Vol. 23, 1990, pp. 297-302  Chayen et al, JOURNAL OF CRYSTAL GROWTH, Microbatch Crystallization Under Oil - A New Technique Allowing Many Small-volume Crystallization Trials, Vol. 122, 1992, pp. 176-180							
	Chayen et al, JOURNAL OF CRYSTAL GROWTH, Is Lysozyme Really the Ideal Model Protein?, Vol. 232, 2001, pp. 262-264				he Ideal Model				
	Chayen et al, PROTEIN SCIENCE, Control of Nucleation in the Crystallization of Lysozyme, Vol. 2, 1993, pp. 113-118								
	Coleman & Hench, CERAMICS INTERNATIONAL, A Gel-derived mesoporous Silica Reference Material for Surface Analysis by Gas Sorption, Vol. 26, 2000, pp. 171-178								
	Cook et al, KEY ENGINEERING MATERIALS, Pore Characterisation and Interconnectivity Studies on bioactive 58 S Sol-Gel Glass, Vols. 192-195, 2001, pp. 625-628								
	D'Arcy et al, JOURNAL OF CRYSTAL GROWTH, A Novel Approach to Crystallising Proteins Under Oil, Vol. 168, 1996, pp. 175-180								
	Dusastre, NATURE, Pore Characterization, Vol. 408, 2000, p. 417  Feher & Kam, METHODS ENZYMOLOGY, Nucleation and Growth of Protein Crystals: General Principles and Assays, Vol. 114, 1985, pp. 77-112				17				

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP  $\Rightarrow$  609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2-92) Sheet 2 of 4

Form PTO-1449 Document Number Application Number 20050515.ORI 10/019,520 INFORMATION DISCLOSURE CITATION Applicant IN AN APPLICATION Naomi Chayen et al (Use several sheets if necessary) Filing Date Group Art Unit May 6, 2005 U.S. PATENT DOCUMENTS EXAMINER DOCUMENT NUMBER DATE NAME CLASS SUBCLASS FILING DATE TNTTTAL IF APPROPRIATE FOREIGN PATENT DOCUMENTS Translation DOCUMENT DATE CLASS SUBCLASS COUNTRY NUMBER YES NO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, Etc.) Hench & West, LIFE CHEMISTRY REPORTS, Biological Applications of Bioactive Glasses, Vol. 13, 1996, pp. 187-241 Hench, CURRENT OPINION IN SOLID STATE & MATERIALS SCIENCE, Sol-gel Materials for Bioceramic Applications, Vol. 2, 1997, pp. 604-610 Hench & West, CHEM. REV., The Sol-Gel Process, Vol. 90, 1990, pp. 33-72 http://proteome.bnl.gov/progress.html, Progress toward structure solution by X-ray Crystallography, January 18, 2005, pp. 1-3 Lenza et al, JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICIN, Surfacemodified 3D Scaffolds for Tissue Engineering, Vol. 13, 2002, pp. 837-842 Li et al, JOURNAL OF APPLIED BIOMATERIALS, An Investigation of Bioactive Glass Powders by Sol-Gel Processing, Vol. 2, 1991, pp. 231-239 Li et al, CHEMICAL PROCESSING OF ADVANCED MATERIALS, Effects of Structure and surface Area on bioactive Powders by Sol-Gel Process, Vol. 56, 1992, pp. 627-633 Malkin et al, JOURNAL OF CRYSTAL GROWTH, Crystallization of Stellite tobacco Mosaic Virus I. Nucleation Phenomena, Vol. 126, 1993, pp. 544-554 McPherson and Schlichta, Heterogeneous and Epitaxial Nucleation of Protein Crystals on Mineral Surfaces, Vol. 239, 1988, pp. 385-387 Orefice et al, JOURNAL OF BIOMEDICAL MATERIAL RESEARCH, Novel Sol-Gel Bioactive Fibers, Vol. 55, 2001, pp. 460-467 Pereira & Hench, JOURNAL OF SOL-GEL SCIENCE AND TECHNOLOGY, Mechanisms of Hydroxyapatite Formation on Porous Gel-Silica Substrates, Vol. 7, 1996, pp. 59-68

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(2-92) Sheet 3 of 4

Form PTO-1449 Document Number Application Number 20050515.ORI 10/019,520 INFORMATION DISCLOSURE CITATION Applicant IN AN APPLICATION Naomi Chayen et al (Use several sheets if necessary) Filing Date Group Art Unit May 6, 2005 U.S. PATENT DOCUMENTS EXAMINER DOCUMENT NUMBER DATE NAME CLASS SUBCLASS FILING DATE TNTTTAL. IF APPROPRIATE FOREIGN PATENT DOCUMENTS DOCUMENT DATE CLASS SUBCLASS Translation COUNTRY NUMBER YES NO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, Etc.) Roether et al, BIOMATERIALS, Development and in vitro Characterisation of Novel Bioresorbable and Bioactive Composite Materials Based on Polylactide Foams and Bioglass for Tissue Engineering Applications, Vol. 23, 2002, pp. 3871-3878 Rosenberger et al, JOURNAL OF CRYSTAL GROWTH, Temperature Dependence of Protein Solubility - Determination and Application to Crystallization in Xray Capillaries, Vol. 129, 1993, pp. 1-12 Sanjoh et al, JOURNAL OF CRYSTAL GROWTH, Spatiotemporal Protein Crystal Growth Studies Using Microfluidic Silicon Devices, Vol. 196, 1999, pp. 691-702 Sanjoh et al. JOURNAL OF CRYSTAL GROWTH, Surface-potential Controlled Simicroarray Devices for Heterogeneous Protein Crystallization Screening, Vol. 232, 2001, pp. 618-628 Saravanapavan and Hench, JOURNAL OF BIOMEDICAL MATERIAL RESEARCH, Low-Temperature synthesis, Structure, and Bioactivity of Gel-Derived Glasses in the Binary CaO-Sio<sub>2</sub> System, Vol. 54, 2001, pp. 608-618 Sepulveda et al, JOURNAL OF BIOMEDICAL MATERIAL RESEARCH, Bioactive Sol-Gel Foams for Tissue Repair, Vol. 59, 2002, pp. 340-348 Sing et al, PURE AND APPL. CHEM., Reporting Physisorption Data for Gas/Solid Systems, Vol. 57, 1985, pp. 603-619 Stamboulis et al, ADVANCED ENGINEERING MATERIALS, Novel Biodegradable Polymer/Bioactive Glass Composites for Tissue Engineering Applications, Vol. 4, No. 3, 2002, pp. 105-109 Stura, PROTEIN CRYSTALLIZATION: TECHNIQUES, STRATEGIES AND TIPS, (ed. Bergfors, T.M.) (International University Line, LaJolla; 1999)

EXAMINER	DATE CONSIDERED

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(2-92) Sheet 4 of 4

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				Applicant Naomi Chayen et al				
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	OTHER DO	CUMENTS (In	cludin	g Author, Title	, Date,	Pertinent	Papers, Etc.)	
	Visuri et al, BIO/TECHNOLOGY, A New Method for Protein Crystallization Using High Pressure, Vol. 8, 1990, pp. 547-549					allization Using		
	Chayen et al, ACTA CRYST., Protein crystallization for Genomics: towards High-throughput Optimization Techniques, Vol. 58, 2002, pp. 921-927  Chayen et al, JOURNAL OF MOLECULAR BIOLOGY, Porous Silicon: An Effective Nucleation-inducing Material for Protein Crystallization, Vol. 312, 2001, pp. 591-595							
	Sakamoto et al, NATURE, Direct Imaging of the Pores and Cages of Three- Dimensional Mesoporous Materials, Vol. 408, 2000, pp. 449-453							
	Saridakis et al, ACTA CRYST, Separating Nucleation and Growth in Protein Crystallization Using Dynamic Light Scattering, Vol. 58, 2002, pp. 1597-1600							
i	Wiencek, ANNU. REV. BIOMED. ENG., New Strategies for Protein Crystal Growth, Vol. 1, 1999, pp. 505-534  Fabbri et al, BIOMATERIALS, Hydroxyapatite-based Porous Aggregates: Physico-Chemical Nature, Structure, Texture and Architecture, Vol. 16, 1995, pp. 225-228  Drenth, J. (1994), PRINCIPLES OF PROTEIN X-RAY CRYSTALLOGRAPHY, Springer-Verlag, New York (Textbook, copy not provided)  Hench, L.L. (1998), SOL-GEL SILICAS, Hayes Publishing Co., New York (Textbook, copy not provided)							
	Iler, R.K. (1979), THE CHEMISTRY OF SILICA, J Wiley & Sons, New York (Textbook, copy not provided)							
	Lowell S., Shields JE. (1984) POWDER SURFACE AREA AND POROSITY. Chapman and Hall (Textbook, copy not provided)							

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